Harris County, Texas vs. International Paper Company, et al.

Cause No. 2011-76724

Report of Philip Cole, MD, DrPH

August 16, 2013

I. Qualifications

I am a physician, Board Certified in Preventive Medicine and licensed to practice medicine in Alabama. I have committed my professional career to research and teaching in epidemiology, the study of the causes of disease in human beings. My focus has been on the development of the methodology of epidemiology, on the assessment of causation and on the classification of chemicals as to carcinogenicity for human beings.

I received my medical degree from the University of Vermont. I obtained the Master of Public Health and the Doctor of Public Health degrees in Epidemiology from Harvard University. I joined the Department of Epidemiology of the Harvard School of Public Health and became a full Professor in 1978. I then served as Professor and Chairman of the Department of Epidemiology at the School of Public Health and Associate Director for Epidemiology at the Comprehensive Cancer Center at the University of Alabama at Birmingham (UAB). I am now a professor emeritus at UAB.

I have authored or co-authored more than 200 papers, most of which were published in the peer-reviewed literature and relate to cancer epidemiology and to epidemiologic methods. These papers include, for example, the identification of the decline of cancer mortality in the U.S. (1). Another, directly relevant to the subject of this case, describes the use of epidemiology for evaluating disease causation (2). Several additional papers of mine (3-5) also relate to the present cases because they address the health effects of 2,3,7,8-tetrachlorodibenzodioxin (TCDD) or to the means of evaluating chemical agents as causes of cancer in man. My publications are listed in the bibliography that is part of the curriculum vitae in Section IX of this Report.

Through more than 45 years of epidemiologic research, teaching and consulting I have become very familiar with all forms of epidemiologic

research and with the scientifically accepted methods for reaching conclusions regarding disease causation in human beings.

My reimbursement for working on the present case is $800 per hour.

II. Materials Relied Upon

1. Various documents provided to me by the Baker Hostetler Law Firm on or about August 10, 2013. These documents consisted primarily of:
   a. Legal documents that I describe as "Complaints" and responses to those Complaints.
   b. The expert Reports and *curricula vita* of Dr. A. S
   c. The Public Health Assessment conducted by the Texas Department of State Health Services for the Agency for Toxic Substances and Disease Registry and an assessment conducted by Integral Consulting Inc.
2. The 15 References listed in Section VIII of this Report.

It is my understanding that the current proceedings relate to three cases: 1. That cited on the title page of this report. 2. That relating to Dao Van Pho, et al. as Plaintiffs and, 3. That relating to Harpster and Harpster as Plaintiffs. It is also my understanding that Discovery is continuing in this case. I reserve my right to modify my opinions in light of any new information that may become available.

III. Epidemiology, The Study of Disease Causation

Epidemiology is the basic science of public health and preventive medicine. It fills the crucial role of establishing, or refuting, suspect agents as causes of all forms of disease in human beings. The great strength of epidemiology is that it studies human beings in their actual life circumstances; in their homes, and in their recreational and occupational

environments. However, because the epidemiologist studies free-living, highly heterogeneous human beings, he or she has no control over their exposures to disease-causing agents or any other aspect of their lives. For these reasons, epidemiologic studies of disease causation tend to produce variable results. In particular, a series of studies of a non-existent causal association will produce incorrect positive results as well as the correct negative ones.

Because epidemiologic research produces variable findings, it is crucial to identify consistent patterns of results both within and among many different investigations before a conclusion is reached that an agent is or is not the cause of a particular disease or type of cancer. And, it is evident that any evaluation of a hypothetical cause-effect relationship must begin with a review of all the available epidemiologic information - that on both sides of the question of causality. All of this information is then evaluated, preferably by using an explicit set of guidelines. The most widely-accepted guidelines are those of Sir Bradford Hill (6), and are usually referred to as "the Hill criteria".

I have reviewed all, or virtually all, of the available epidemiologic information on TCDD, the agent alleged in this case to cause cancer, heart disease and other diseases in human beings. More specifically, my colleagues and I recently completed a comprehensive review of the literature on TCDD and cancer (4). We concluded that the available scientific evidence does not support the hypothesis that TCDD causes cancer in human beings. In conducting our review we used the Hill criteria. This was the second comprehensive review that I have published evaluating the carcinogenicity of TCDD for human beings. The first (3) was published 10 years ago.

The material described in my recent review of TCDD (4) and the sum of my evaluations immediately below of the evidence in terms of the Hill criteria constitute the basis for my opinion that the available scientific

evidence does not support the hypothesis that TCDD is a cause of cancer in human beings.

Hill originally described nine criteria of causality but with the passage of nearly 50 years, five of them have become recognized as distinctly important. I will describe these five major criteria and illustrate them briefly with the alleged causal relationship between TCDD and "all cancer" as the "disease" of interest.

Hill's important criteria are:

1. *Strength of association* - An association is "strong" when persons exposed to TCDD experience a clear and consistent excess risk of cancer as compared to the normal, or "baseline", risk of cancer among persons not exposed to TCDD. Epidemiologists consider that at least a 2-fold increased risk among exposed persons usually is necessary for an association to be considered causal. A strong association (SMR=500 or greater) characterizes nearly all true cause-effect relationships. (SMR, the standardized morbidity or mortality ratio, is used by epidemiologists as a measure of disease risk - a value of 100 designates a "normal" risk while an SMR of 200 designates a doubling of risk, etc.) The relationship between TCDD and all cancer is extremely weak (SMR=130) and, in fact, often no excess risk at all has been found. My summary of the recent literature, presented below in Section IV of this Report, shows the TCDD-cancer association to have an SMR of only 110.

2. *Consistency* - "Consistency" means that the relationship between TCDD and all cancer is nearly always found by different investigators studying different groups of TCDD-exposed persons. This criterion is not met with respect to TCDD and "all cancer".

3. and 4. *Plausibility* and *Coherence* - These two criteria are most easily described together. They mean, "does the association seem plausible in a biologically mechanistic sense?" and "is there scientific evidence that contradicts it?" The supposed causal relationship between TCDD and all

cancer is not plausible or coherent. It is implausible because there is no "pan-carcinogen" for human malignancy. The broadest-spectrum human carcinogen, ionizing radiation, is a physical agent, not a chemical, and it directly and physically breaks DNA within the cell. Yet, even this potent carcinogen produces only about 10 or 12 of the 20 or so major forms of human cancer. No known chemical carcinogen produces more than three or four.

The hypothetical TCDD-all cancer relationship is not coherent because it is directly contradicted by a number of studies that fail to show any excess of cancer among highly-exposed persons. The most recent of these studies are described below and their principal data are given in the Table in Section VIII of this Report.

5. *Dose-response* -This is an important criterion not only in epidemiology but in all the biomedical sciences. It means that the increased risk of disease is proportional to the extent of the increased exposure to TCDD. The TCDD-all cancer relationship repeatedly has failed to meet this axiom of disease causation.

The minor Hill criteria are: *temporality, experiment, specificity and analogy*. I will be glad to describe them if requested to do so.

IV. Tetrachlorodibenzodioxin and Health

There have been many reviews, risk assessments and other approaches to evaluating the carcinogenicity and health effects of TCDD. The most comprehensive and balanced of these compilations was published in 2006 by the National Research Council/National Academy of Science (7). Though now seven years old, this review remains timely. It reviewed the position of the U.S. Environmental Protection Agency (EPA) that TCDD should be considered a known human carcinogen. The National Research Council (NRC) stated three objections to the EPA's position: *i*. TCDD has not been shown consistently to increase the risk of any form of cancer. *ii*. The biologic mechanism whereby

TCDD causes cancer in animals is not known to act in the same way in human beings. *iii*. The EPA assessment was unbalanced and favored positive findings over negative findings of equal quality. In fact, the NRC implies that the EPA should reconsider its position and, perhaps, re-classify TCDD as only a "likely" human carcinogen.

Another Agency that has reviewed the carcinogenicity of TCDD is the International Agency for Research on Cancer (IARC), the cancer research arm of the World Health Organization. The most recent review of TCDD by IARC was published in 2012 (8). It states that the available evidence of TCDD"s carcinogenicity for human beings is "limited" The evidence does not rise to the level where it could be described as "sufficient" - IARC's highest category.

A third agency that has reviewed the question of TCDD and disease is the Institute of Medicine (9). This review was done on behalf of the U.S. Office of Veterans Affairs. The purpose was to assist that Office in deciding which diseases occurring among U.S. veterans of the Vietnam war were entitled to special compensation because of their handling of Agent Orange (containing TCDD). The Institute of Medicine actually has conducted a series of nine reviews, the most recent appearing in 2010. The IOM's findings remain that no causal relationship exists between Agent Orange (TCDD) and any disease, except chloracne, a very uncommon skin condition. They did identify four forms of cancer for which they considered that there was "sufficient evidence of association" but did not indicate that a causal relationship existed.

In addition to the reviews of TCDD and cancer, many original research studies have been reported. These studies relate to exposure to TCDD in settings where residential or worker populations had exposure, often heavy exposure, to TCDD. This research describes no strong or consistent increases in "all cancer" or in any form of cancer among persons exposed to TCDD. For

this presentation I have selected from my 2011 review the five major studies (10-14) that were first published, or updated, within the last 10 years. I include my review paper here by citation (4) as part of this Report.

1. The first paper (10) published in 2004 relates to a group of men who, of all the occupational groups studied, were probably the most heavily exposed to TCDD. These men were the so-called "Ranch Hand" workers. They were responsible for loading and cleaning the American aircraft that were spraying Agent Orange over the jungles of Vietnam during the war. These men were followed-up through 2000 (more than 25 years in some cases) and were found to have no excess of mortality from cancer (Table in Section VIII of this Report).

2. The most well-recognized residential study of the health effects of TCDD relate to the "Seveso Accident" (11). In 1976 an accident occurred at a manufacturing facility in Seveso, Italy. A large amount of TCDD was expelled into the air as a result. Many of the residents of Seveso were found subsequently to have extremely high blood levels of TCDD. Yet, the most recent study (11) of these people, including those who lived closest to the accident site, showed that they experienced no increased risk of cancer.

3-5. References (12-14). A series of three independent studies of chemical workers in various industries were reported in 2009 and 2010. Two of these studies (12,13) reported no statistically significant excess of cancer among the workers. The study from The Netherlands (14) reported that the workers had a 37% increased risk of cancer, a finding that was just barely statistically significant.

In sum, the five studies just reviewed, all consisting of persons heavily exposed to TCDD, show a minimal 10% increase (combined SMR of 110) among them. This minimal excess is just barely statistically significant and may be attributed readily to factors other than TCDD. There are three observations of importance: 1. An SMR of 110 is very weak. 2. Four of the

five studies failed to find any association of TCDD with cancer. 3. No individual form of cancer was consistently in excess among the studies.

V. The Texas/ATSDR Public Health Assessment

A Public Health Assessment was prepared by the Texas Department of State Health Services (TDSHS) for the U.S. Agency for Toxic Substances and Disease Registry (ATSDR). In reviewing this Assessment my focus was on the estimates of the risk of cancer from various scenarios of exposure to TCDD.

There are several fundamental aspects of the Texas risk assessment that may not be clear from the available document but are crucial to the interpretation of the results relating to cancer risks:

First, most risk assessments, including this one, have the trappings of a science. However, as I have indicated elsewhere (2), they are not exercises in science but in public health policy. In most cases, again including this one, the results relating to estimates of disease risk are difficult to defend. It is commendable that in the present assessment, this difficulty is expressed clearly. On p. 126 of the Assessment it is stated that, "It should be noted that, because of the conservative models used to derive oral and dermal slope factors, the above approach provides a theoretical ***upper bound estimate*** of the excess risk; the true or actual excess risk is unknown and ***could be as low as zero***. (Emphasis added.)

However, even this frank description of the uncertainty in the estimates of disease risk fails to convey to most readers - certainly to lay readers - their full limitations. Two things are missing: The first is an explanation of the uncertainty of the assumptions that underlie the sophisticated procedures used. The second is the absence of perspective as to how small the risks are, even if they were accurate.

Regarding the uncertainties: four assumptions are listed on p. 32 of the report and are described as "uncertainty factors". I have rewritten each

of these uncertainties in an effort to make them more comprehensible to the layman. I have not changed their meaning in any way, but for clarity I have expressed them as "assumptions" rather than as "uncertainties":

1. Assume that the dose of TCDD given to animals in a research study can be extrapolated (presumably linearly) to an equivalent human dose (presumably on a body weight basis). (By "equivalent" I understand a built-in implicit assumption that TCDD can cause cancer in man.)

Both aspects of this assumption are unlikely to be true as human beings are far more resistant to chemical carcinogens than are most animal species. In fact, most experiments use animals that are inbred to become especially sensitive to carcinogens.

2. *Assume that some sub-groups of human beings are particularly susceptible to cancer.*

This is almost certainly true with respect to very small groups of people and for a few rare cancers. It is not clear how, if at all, this assumption was used in making the risk assessments.

3. *Assume that the lowest exposure level that produces cancer in animals also would do so in human beings and ignore dose levels that do not produce cancer in animals.*

This assumption has no basis in fact for the same reasons given with respect to the first assumption - humans are relatively resistant to carcinogens.

4. *Assume that deficiencies in the data - whether recognized or not - do not actually exist.*

No comment is required on this.

With regard to perspectives on the size of the risk estimates, particularly those relating to cancer: The authors of the Texas Risk Assessment do frankly acknowledge that their cancer estimates may be too high and possibly could be zero. However, they point out how very low it is only in Appendix D. Even there, perspective is still lacking. In reality, a typical risk estimate in the Texas Public Health Assessment is an increased risk of one case of cancer per 100,000 people who eat eight ounces of fish per day for about 78 years. To interpret this risk correctly, it must be understood that, of 100,000 Americans, about 40,000 or 40% will develop cancer during their lives (15). Thus, the estimated increase of "1 per 100,000" means that, instead of 40,000 cases of cancer occurring in 100,000 people, there would be 40,001. An "increased risk" this minute is so small as to be inconsequential. *It never could be detected, measured or known to exist...or not to exist.* Thus, even the representation in the report that the true risk estimate "could be zero", while somewhat accurate, is an over-estimate. A more accurate statement is that a risk of the size reported (1 per 100,000 lifetimes) is, in fact, zero. This statement is justified not only by the minute risk offered by the Texas report but also by a realization that this estimate is predicated on a series of improbable assumptions that cause it to be as large as possible.

VI. Reports of Plaintiff's Experts

I have reviewed the Reports of two of the plaintiff's experts and offer the following comments:

a. Dr. Arnold Schecter

Dr. Schecter's Report describes his experience studying Agent Orange and dioxin. This work appears to be focused on exposure assessment. It does not address disease occurrence subsequent to dioxin exposure. Dr. Schecter endorses the Report of Dr. J. Olson in this case but does not appear to offer

his own opinion that TCDD causes cancer, or any other disease, in human beings.

b. Dr. W. Snodgrass

Dr. Snodgrass opines that "dioxins...are reported to be statistically associated with some cancers in humans in high dose exposures ***resulting in*** greater risks for cancer... (Emphasis added). No specific research is cited to support this statement which appears to imply causation. Dr. Snodgrass also refers to a "Differential Diagnosis" (p. 3) but it is unclear what this addresses. He also refers to "methodology" which includes Koch's postulates as applied to toxicology. He does not state how the data he relies upon as evidence for a causal relationship between TCDD and cancer fulfill Koch's postulates. His methodology also includes the "Hill criteria" for scientific evidence. He does not describe how, in his opinion, the available scientific evidence fulfills the Hill criteria.

VII. Opinion

It is my opinion that 2,3,7,8- tetrachlorodibenzodioxin (TCDD) is not carcinogenic to human beings.

This opinion is based on a wealth of epidemiologic and other scientific information that is weak, inconsistent and otherwise insufficient to support the hypothesis that TCDD cause cancer in human beings.

My opinion is also supported by the U.S. National Academies and by the International Agency for Research on Cancer which judges the evidence that TCDD causes cancer in man to be ***limited***.

It also is my opinion that the risk estimates relating to issues in this case, and prepared by the Texas Department of State Health Services for The Agency for Toxic Substances and Registry, rest on weak assumptions. In any case, the cancer risk estimtes are more consistent with TCDD, at the

doses studied, as having no carcinogenic effect rather than the slight effect reported.

I hold both of these opinions to a reasonable degree of scientific certainty.

Philip Cole, MD Aug 16, 2013

VIII. References and Table

VIII a. References

1. Cole P, Rodu B: Declining cancer mortality in the United States. *Cancer* 78:2045-2048, 1996.

2. Cole P: Causality in epidemiology, health policy and law. *Environmental Law Reporter* 26(6):10279-10285, 1997.

3. Cole P, et al: Dioxin and cancer: A critical review. *Regul Toxicol Pharmacol* 38:378-88, 2003.

4. Boffetta P, et al: A critical review of epidemiologic studies. *Crit Reviews in Toxicol* 41:622-636, 2011.

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8. International Agency for Research on Cancer: IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Volume 100F: Chemical agents and related occupations. Lyon, France, 2012. Available at: www.iarc.fr.

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10. Akhtar F, et al: Cancer in US Air Force veterans of the Vietnam war. *J Occup Environ Med* 46:123-136, 2004.

11. Pesatori A, et al: Cancer incidence in the population exposed to dioxin after the "Seveso accident": Twenty years of follow-up. *Environ Hlth* 8:39-44, 2009.

12. Collins J, et al: Mortality among trichlorophenol workers with exposure to 2,3,7,8-tetrachlorodibenzo-p-dioxin. *Am J Epidemiol* 170:501-506, 2009.

13. McBride D, et al: Mortality in workers exposed to 2,3,7,8-tetrachlorodibenzodioxin at a trichlorophenol plant in New Zealand. *J Occup Environ Med* 51:1049-1056, 2009.

14. Boers D, et al: Cause-specific mortality of Dutch chlorophenoxy herbicide manufacturing workers. *Occup Environ Med* 67:24-31, 2010.

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VIIIb. Table

Observed and expected numbers of cancer deaths, SMRs and 95% two-sided confidence intervals. Five studies of persons highly exposed to TCDD.

	Year	Location	Subjects	Obs.	Exp.*	SMR	CI	Author (R)
1.	2004	Vietnam	US Vets	146	136	108	91-126	Akhtar (10)
2.	2009	Seveso	Residents	44	43	103	76-138	Pesatori (11)
3.	2009	USA	Chem. Workers	177	177	100	85-115	Collins (12)
4.	2009	New Zealand	Chem. Workers	61	55	111	86-143	McBride (13)
5.	2010	Netherlands	Chem. Workers	125	91	137	115-163	Boers (14)
	Total	-	-	553	502	110	101-120	-

*Some expected numbers estimated by P. Cole from data in the references.

CURRICULUM VITAE

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Academic Appointment: Professor *Emeritus*
Department of Epidemiology
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Education:

Michigan State University	B.A.	1960
University of Vermont	M.D.	1965
Harvard University	M.P.H.	1967
Harvard University	Dr.P.H.	1970

Previous positions:

Professor
(Chairman, 1981-94)
(Emeritus, 1999)
Department of Epidemiology
School of Public Health
University of Alabama at Birmingham

Senior Scientist 1979-99
Associate Director for Epidemiology 1979-93
Comprehensive Cancer Center
University of Alabama at Birmingham

Assistant and Associate Professor 1969-78
Professor 1978-79
Department of Epidemiology
Harvard School of Public Health

Consultant in Epidemiology and Biostatistics
International Agency for Research on Cancer 1977-78

Surgical Intern, Royal Victoria Hospital
Montreal 1965-66

Certification and Professional Societies:

Licensed, Alabama Medical Licensure Commission 1981-2011

Licensed, Board of Registration in Medicine, Commonwealth of Massachusetts 1966-80

Diplomate, National Board of Medical Examiners 1966

Certified, American Board of Preventive Medicine 1971

Member, American Epidemiologic Society 1973-79

Honorary Fellow, American College of Epidemiology 1997

Prepared: July 1, 2013

Honors:

American Cancer Society, Faculty Research Award	1973-78
Visiting Lecturer on Epidemiology Harvard School of Public Health	1979-99
Gordon Richards Memorial Lecturer Ontario Cancer Treatment and Research Foundation	1979
John Whittick Memorial Lecturer Canadian Cancer Society	1980
Kammer Merit in Authorship Award American Occupational Medical Association	1982
John Rankin Visiting Professor of Occupational and Preventive Medicine University of Wisconsin, Madison	1983
Eleanor Leader Memorial Lecturer University of Toronto, Toronto	1985
Grand Prix Lacassagne du La Ligue Nationale Francaise contre le Cancer, (with B. MacMahon, J. Brown and D. Trichopoulos)	1986
First Annual President's Award Outstanding Teacher School of Public Health, UAB	1991
Cutter Lecturer Harvard School of Public Health	1996
Myrick Lecturer Injury Control Research Center, UAB	1996
Lecturer Delta Omega Society, UAB	1997
First Recipient Distinguished Faculty Investigator Award School of Public Health, UAB	1998
Distinguished Academic Achievement Award College of Medicine, University of Vermont	2000

Major Committees:

Scientific Advisory Committee Division of Cancer Cause and Prevention National Cancer Institute	1978-80
General Motors-United Auto Workers Occupational Health Advisory Board	1982-87
Prevention, Cancer Control (Chairman) Steering Committee, National Planning Effort National Cancer Institute	1984-85
Mott Prize Selection Committee General Motors Cancer Research Foundation	1985
Board of Scientific Counselors Division of Cancer Prevention and Control National Cancer Institute	1986-90

Major Committees continued:

Advisory Council on Epidemiology	
Electric Power Research Institute	1986-90
Program Project Review Committee	
National Cancer Institute of Canada	1993
Research Professor Selection Committee	
American Cancer Society	1994
EPA-Dow Elanco Review Committee	
Health Effects of Chlorpyrifos	1997
American Council on Science and Health	
Committee on Phthalates	1999

Teaching:

Harvard School of Public Health	
The epidemiology of chronic diseases	1969-72
The epidemiology of neoplastic diseases	1973-77
Epidemiologic methods	1976
Principles of epidemiology	1978-79
University of Minnesota-Graduate Summer Session	
The epidemiology of cancer	1971-80
Principles of epidemiologic research	1985
Fundamentals of epidemiology	1986-91
International Agency for Research on Cancer	
Cancer epidemiology	1974-80
University of Massachusetts-Graduate Summer Session	
Principles of epidemiology	1981-85
Cancer epidemiology	1982
Tufts University-Graduate Summer Session	
Epidemiologic bases of public health policy and law	1986,87
Principles of epidemiology	1994-96
University of Alabama at Birmingham	
Epidemiology of cancer	1980
Principles of epidemiologic research	1980-95
Advanced epidemiologic methods	1981
Doctoral seminar	1981-91,99,02
Introduction to epidemiology	1996,97,00
Mediterranean School of Epidemiology and Biostatistics	
National Research Council of Italy, Siracusa, Sicily	
Introduction to Epidemiology	2003

Research Interests:

Causality in epidemiology, health policy and law
Innovative approaches to smoking cessation
Occupational and chemical carcinogenesis
Health effects of electromagnetic fields

Other:	Chairman of the Faculty, School of Public Health, UAB	1991-95

Publications

1. Cole P, MacMahon B, Aisenberg A: Mortality from Hodgkin's disease in the United States: Evidence for the multiple-aetiology hypothesis. *Lancet* 2:1371-1376, 1968.

2. Cole P, Gutelius J: Paraplegia resulting from the use of the subclavian artery as a shunt source during resection of the descending thoracic aorta. *Ann Surg* 169:293-294, 1969.

3. Rapoport A, Cole P, Mason J: Correlates of survival after initiation of chemotherapy in 142 cases of Hodgkin's disease. *Cancer* 24:377-381, 1969.

4. Cole P, MacMahon B: OEstrogen fractions during early reproductive life in the aetiology of breast cancer. *Lancet* 1:604-606, 1969.

5. MacMahon B, Cole P: Endocrinology and epidemiology of breast cancer. *Cancer* 24:1146-1150, 1969.

6. Cole P, Gutelius J: Neurologic complications of surgery on the descending thoracic aorta. *Can J Surg* 12:435-443, 1969.

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9. Cole P, Monson R, Haning H, Friedell G: Smoking and cancer of the lower urinary tract. *N Engl J Med* 284:129-134, 1971.

10. Mirra A, Cole P, MacMahon B: Breast cancer in an area of high parity: Sao Paulo, Brazil. *Cancer Res* 31:77-83, 1971. Reprinted in Portuguese in *Rev Assoc Med Bras* 18:357-364, 1972.

11. Cole P: Coffee-drinking and cancer of the lower urinary tract. *Lancet* 1:1335-1337, 1971.

12. MacMahon B, Cole P, Brown J, et al: OEstrogen profiles of Asian and North American women. *Lancet* 2:900-902, 1971.

13. Hoover R, Cole P: Population trends in cigarette smoking and bladder cancer. *Am J Epidemiol* 94:409-418, 1971.

14. Cole P, MacMahon B: Attributable risk percent in case-control studies. *Br J Prev Soc Med* 25:242-244, 1971.

15. Allen D, Cole P: Viruses and human cancer. *N Engl J Med* 286:70-82, 1972. Reprinted in *Ca - Cancer Journal for Clinicians* 23:127-136, 1973 and in *Diagnostic* 4:189-194, 1973.

16. Trichopoulos D, MacMahon B, Cole P: Menopause and breast cancer risk. *J Natl Cancer Inst* 48:605-613, 1972.

17. Cole P, Hoover R, Friedell G: Occupation and cancer of the lower urinary tract. *Cancer* 29:1250-1260, 1972.

18. MacMahon B, Cole P: The ovarian etiology of human breast cancer. *Current Problems in the Epidemiology of Cancer, Lymphomas and Leukemias. Recent Results Cancer Res* 39:185-192, 1972.

19. Cole P: Epidemiology of Hodgkin's disease. *JAMA* 222:1636-1639, 1972.

20. MacMahon B, Cole P, Brown J: Etiology of human breast cancer: A review. *J Natl Cancer Inst* 50:21-42, 1973.

21. Hoover R, Cole P: Temporal aspects of occupational bladder carcinogenesis. *N Engl J Med* 288:1040-1043, 1973.

22. Cole P: Epidemiologic studies and surveillance of human cancers among personnel of virus laboratories. In Hellman A, Oxman MN, Pollack R (eds), *Biohazards in Biological Research*. Cold Spring Harbor Laboratory, New York 1973.

23. Cole P: Hypotheses regarding the etiology of breast cancer. *Seventh National Cancer Conference Proceedings*. JB Lippincott Company, Philadelphia, 1973.

24. Cole P: A population-based study of bladder cancer. In Doll R, Vodopija I (eds), *Host Environment Interactions in the Etiology of Cancer in Man*. International Agency for Research on Cancer, Lyon, France, pp 83-87, 1973.

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